

Claims

1. A method for a physical pre-treatment of an active substance, characterized in that it comprises adding a poor solvent or a mixture of solvents to the active substance or to a mixture of the active substance with other excipients, the solubility of the substance in said solvent being less than about 0.1 g/L, followed by drying.
2. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that said method comprises humidifying with water.
3. A method for a physical pre-treatment of an active substance according to claim 2, characterized in that the aqueous solution may contain various pharmaceutically acceptable excipients such as binders, buffers, emulgators, surfactants and others.
4. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the part of the active substance in the mass of the whole formulation is over about 30%.
5. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the part of the active substance in the mass of the whole formulation is over about 40%.
6. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the active substance is practically insoluble in the solvent used.

ART 2A

7. A method for a physical pre-treatment of an active substance according to claim 6, characterized in that the solvent used is water, wherein the solubility of the active substance is under about 0.1 g/L.
8. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the active substance, if micronized, is difficult to be directly tabletted or encapsulated.
9. A method for a physical pre-treatment of an active substance according to claim 1, characterized in that the particles thereof are large, brittle and/or porous.
10. A method for a physical pre-treatment of an active substance according to claims 1 to 9, characterized in that the active substance is clarithromycin.
11. A method for a physical pre-treatment of an active substance according to claim 10, characterized in that clarithromycin is micronized.
12. A method for a physical pre-treatment of an active substance according to claim 11, characterized in that the pre-treated, micronized clarithromycin enters a direct mixture for tableting or encapsulating as a starting material.
13. A method for a physical pre-treatment of an active substance according to claims 1 to 12, characterized in that the obtained cores are coated.
14. A method for a physical pre-treatment of an active substance according to claim 13, characterized in that the coating also contains a polymer having viscosity of up to above 15 mPas.

ART 21/2000

15. A method for a physical pre-treatment of an active substance according to claim 14, characterized in that the coating contains at least about 10% of a polymer having viscosity of up to about 15 mPas.

16. A method for a physical pre-treatment of an active substance according to claims 14 to 15, characterized in that the polymer used in the coating has a viscosity of over about 6 mPas.

17 A pharmaceutical formulation with clarithromycin or analogues thereof, characterized in that the active substance is modified according to the method of claims 1 to 16.

18 A pharmaceutical formulation prepared according to the method of claims 1 to 16 for use in medicine for the treatment and prevention of diseases.

19 The use of a film coating composed of a combination of polymers having viscosities of up to about 15 mPas and about 6 mPas for coating tablet cores manufactured according to the method of claims 1 to 12.

ART 34 AMDT